

FEB 13 1997

K 963285

P172

**510(k) Summary for the Expansion of the Indications for Use of the
Electro Medical Systems SA
EMS SWISS LITHOCLAST LITHOTRIPTER
(per 21 CFR 807.92)**

1. Date Prepared: August 16, 1996
2. Sponsor/Applicant: Electro Medical Systems SA
Chemin de la Vaurpilliere 31
CH-1260 Nyon
Switzerland
3. Contact Person: Manfred Schulz
4. Device Name:

Trade/Proprietary Name: EMS SWISS LITHOCLAST LITHOTRIPTER
Common/Usual Name: Endoscopic intracorporeal pneumatic lithotripter
Classification Name: Electrohydraulic Lithotripter
5. Device Classification: Class III
6. Predicate Devices:
 - EMS SWISS LITHOCLAST LITHOTRIPTER (for ureteral and bladder stones)
K951531
 - Wolf 2270 Ultrasound Generator and Sonatropes
 - Wolf 2280 Electrohydraulic Lithotripter (K923487)
 - Candela LaserTripter (K863642/K885255)
7. Intended Use:

The EMS SWISS LITHOCLAST LITHOTRIPTER is intended for use in fragmenting urinary tract calculi (renal, ureteral, and bladder) through rigid or semirigid endoscopes.

1K963285

P272

8. Operational and Technological Characteristics:

The operational and technological characteristics of the LITHOCLAST are unchanged.

A retrospective clinical study of the results on 83 kidneys with renal stones treated by two investigational sites was provided to support the safety and effectiveness of the EMS SWISS LITHOCLAST for treatment of renal stones. The clinical data demonstrates that the EMS SWISS LITHOCLAST is substantially equivalent in safety and effectiveness to that of the predicate devices cited above as reported in the medical literature.